PATIENT INFORMATION SHEET

STUDY TITLE

An observational cohort study of people attending the ED with symptoms of Acute Aortic syndrome (AAS)

Short title: **DAShED Study (Diagnosis of Aortic Syndrome in the Emergency Department)**

IRAS ID 315948; Chief Investigator: Dr Rachel McLatchie; Local Principal Investigator: _____

1. INTRODUCTION

Acute aortic syndrome (AAS) is a potentially catastrophic problem involving the aorta, a large artery supplying blood from the heart to the rest of the body. AAS affects about 4000 people every year in the UK. It can be difficult to diagnose, as the symptoms can be very variable, and may mimic other emergency problems. Up to one in three patients with AAS are not diagnosed in the emergency department (ED), and one in four are not diagnosed until 24 hours after arriving in the ED. AAS is diagnosed using a special scan called a CT aortogram (CTA). However, scanning everyone with symptoms associated with AAS would be extremely costly, would expose many to unnecessary radiation and would delay CT for patients with other conditions. Clinical scores based on patient characteristics and a blood test could be used routinely to decide who needs a CTA. However, we don't know how many people would get scan unnecessarily if we use these scores. We plan to study what effect using these clinical scores and blood tests would have, so that we can plan further research. We will collect information from all patients attending several UK EDs with symptoms of AAS during a one-month period. This study does not involve any extra treatments or tests and involves no extra questions other than those that your clinician would ask you routinely. We are not asking for consent for this study because it involves no change to your clinical assessment or care. All information obtained will be fully anonymised.

2. WHY HAVE I BEEN INVITED TO TAKE PART?

You are being invited to take part because you have attended the ED with either chest, back or abdominal pain, collapse, or symptoms related to blood not reaching a vital organ (e.g. a stroke). These are known to be symptoms associated with AAS, but AAS is rare and it is more likely that there is another cause for your symptoms.

3. WHAT IS THE PURPOSE OF THE RESEARCH?

This entirely observational study aims to understand the characteristics and management of patients presenting to the ED with any symptoms that could be due to AAS, to study the usefulness of risk scores and a blood test to decide which patients need to have a CTA scan.

4. WHAT WILL HAPPEN IF I TAKE PART?

We will collect information from your medical records about the events causing your ED attendance, your physical examination, your test results, your diagnosis, and whether you are admitted to hospital. The clinical team will also review your hospital record after 30 days for your hospital discharge diagnosis. To take part in the study you do not have to do anything. The information we need is the information you will be providing to your clinician during your routine care. We won't need to ask you any further questions, either today or later.

You are free to withdraw from the study at any point by speaking with your treating nurse or clinician or contacting the local study Principal Investigator at **insert Local Principal Investigator email** or by telephone on **insert Local Principal Investigator telephone no.**

5. ARE THERE ANY PAYMENTS OR EXPENSES FOR THIS STUDY?

No, there are no associated payments or expenses by being involved in this study.

6. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There will be no direct benefit to you by taking part. However, this research may improve the way that AAS is recognised and investigated in the future and could improve the care for someone who comes to the hospital with the same problem as you.

7. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Personal data will be collected as part of the study by your clinical team and held for 30 days, at which point it will be destroyed. We have minimised any data risk through use of a specialist medical database service which conforms to all current international standards. We are treating this project like any other research study, with strict oversight and regular review.

8. WHAT ABOUT CONFIDENTIALITY- HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you and your medical records for this research project. This information will include your hospital number, NHS number, Health and Care number, or Community Health Index (CHI) number (patients in Scotland only). The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. The information collected will *not* include any personal identifiers and all information will be fully anonymised.

People will use this information to do the research or to check your records to make sure that the research is being done properly. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. All the information we collect during the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

We will keep all information about you safe and secure.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- from our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the Data Protection Officer at NHS Lothian: Lothian.DPO@nhs.net or call 0131 465 5444

9. WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

This study will be written up as a publication for a medical journal and the team will aim to present the findings at relevant conferences. You will not be identifiable from any published results.

10. WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is organised by NHS Lothian researchers and funded by the Royal College of Emergency Medicine. The study is Sponsored by University of Edinburgh and NHS Lothian.

11. WHO HAS REVIEWED THIS STUDY?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from [insert REC name]. NHS Management Approval has also been given.

13. WHAT IF THERE IS A PROBLEM?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any further questions about the study, please contact the local study team on [contact details].

If you would like to discuss this study with someone independent of the study, please contact Professor Alasdair Gray (NHS Lothian) at emerge@nhslothian.scot.nhs.uk.

If you wish to make a complaint about the study, please contact: [insert contact details]